DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

g3777d

One Montvale Avenue
Stoneham, Massachusetts 02180
Telephone: 781.596.7700
Facsimile: 781.596.7899

December 20, 2002

WARNING LETTER

NWE–04–03W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ronald Wallach, President and CEO
Wallach Surgical Devices, Inc.
235 Edison Road
Orange, CT 06477

Dear Mr. Wallach:

On September 30, 2002, the Food and Drug Administration completed an inspection of your firm located at 235 Edison Road in Orange, CT. Our investigator collected labeling for **Wallach Ferric Subsulfate Solution** bearing the following specifications—

"**Contents**.....	Ferric subsulfate 26% is preserved with Methylparaben (USP) 0.06% and Propylparaben (USP) 0.02%, PVP K-30 USP/NF 8.5%, PVP K-90 USP/NF 8%, Glycerin USP 10%, Water 47.42%."
"**Indications and usage** ...	Ferric subsulfate is indicated as a styptic agent used for achieving local hemostasis (the control of bleeding), which is accomplished by a combination of direct pressure with a large cotton swab and application of a hemostatic agent such as Monsel's solution (Ferric Subsulfate)."

These representations clearly establish that **Wallach Ferric Subsulfate Solution** is a drug as defined in Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(g)(1).

This inspection documented a deviation from current Good Manufacturing Practice (cGMP) Regulations set forth in Title 21, Code of Federal Regulations (CFR) Parts 210 and 211. Although Wallach Ferric Subsulfate Solution is manufactured at another facility for you under contract, your facility conducts packaging, labeling, testing, and/or quality control activities that are covered by the cGMP requirements. See 21 CFR § 210.3(b)(12). The following deviation causes this drug product to be adulterated within the meaning of Section 501(a)(2)(B) of the Act, 21 U.S.C. § 351(a)(2)(B):

- Failure to review production and control records to determine compliance with approved procedures before a batch is released or distributed; and to investigate thoroughly any unexplained discrepancy or a failure of a batch to meet a specification; and to make a written record of the investigation that includes your conclusions and follow-up, as required by 21 CFR § 211.192. Specifically, your firm accepted delivery from your contract manufacturer of a lot of Wallach Ferric Subsulfate Solution (Lot IE135D) that contained only [redacted] iron (Fe), a concentration that is well below your firm's finished product specification of [redacted]. Moreover, your firm did not conduct or document an investigation of this unexplained discrepancy.

The inspection also confirmed that your firm manufactures the LL 100 Cryosurgical System, which is a medical device as defined in Section 201(h) of the Act, 21 U.S.C. § 321(h). The inspection revealed that this device is adulterated within the meaning of Section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformity with the Quality System (QS) Regulation, Title 21, Code of Federal Regulations (CFR) Part 820, as follows:

- Failure to document and authorize in writing the justification for the disposition of nonconforming product, as required under 21 CFR § 820.90(b)(1). Your firm determined that some or all of a shipment of core valves, a component used in the assembly of the LL 100 cryosurgical device, contained rubber cups (or seals) composed of [redacted] rather than [redacted] which is the specified material. The shipment of nonconforming valves was received on or about July 26, 2001. As a corrective action, the remaining valves were purged from inventory on or about September 14, 2001.

  However, for this period of more than a month, valves with nonconforming seals were used in the assembly of new devices as well as for repairing devices that had been returned to the firm. Once your firm realized that nonconforming core valves had been used, it did not document and authorize in writing the justification for allowing the products with nonconforming to remain in the marketplace.

- Failure to analyze all sources of quality data to identify existing and potential causes of nonconforming product and other quality problems, as required

under 21 CFR 820.100(a)(1). Specifically, your firm did not treat information relating to product repairs as a source of quality data to assist you in identifying causes of quality problems.

The following table represents a series of repairs for LL 100 units produced between March and September 2001:

Manufacturing Code	Date of Production	Date of Repair
FAT3P	March 2001	September 7, 2001
FAT3AS	March 2001	May 16, 2001
FAT4AH	April 2001	January 10, 2002
FAT4B	April 2001	May 30, 2001
FAT6BY	June 2001	August 23, 2001
FAT9CM	September 2001	January 14, 2002

None of these repairs were recorded as complaints in accordance with Wallach's *Complaint Control* SOP QAP #001, which identifies non-routine servicing as a type of complaint. At least three of these repairs occurred within 90 days of the device's manufacture. Two of the repairs (to units coded FAT3P and FAT6BY), which were performed with potentially faulty valves, occurred *after* the opening of the firm's *Quality Problem Report* (CAPA 0011) on July 27, 2001.

We have reviewed your response to the Form FDA 483 (Inspectional Observations) that was presented to your firm at the conclusion of this inspection. The corrections promised in your response will be verified during our next inspection. In the meantime, we have concerns about the following items:

- In your response to Observation 3, you refer to an operating procedure that will be developed for compiling and analyzing customer complaints. Under the new procedure, you personally, in your capacity as President of the firm, will be notified of "rejection" rates exceeding [redacted] and will then be required to "determine the appropriate action."

  Please confirm whether this [redacted] action level will apply to all medical devices made by your firm, regardless of classification or risk. Also, please justify the choice of [redacted] as an action level.

- Your response to Observation 4 describes a modification to WSD Form QC 017. This form appears to be a generic acceptance form. The example collected during our inspection contained a handwritten entry for ferric subsulfate as the product. All "characteristics" for this product (WKM, 8 ml Bottle, Exp Date) are also handwritten entries on this form. Under the section "%AQL," handwritten entries of the lot number and expiration date are recorded for each Order Number (of ferric subsulfate) received.

This does not appear to represent a revision in a form, but simply additional requirements regarding the information that will presumably continue to be entered by hand each time. Please confirm the nature of your proposed correction.

- Observation 6 concerned a lot of Wallach Ferric Subsulfate Solution with an apparent iron content of [redacted] (versus a minimum specification of [redacted]. This corresponds to a potency of less than [redacted] (relative to the figure of [redacted]. What justification, other than "to date no customer complaints have been received," do you offer for not being concerned about the effectiveness of product that may still be in commercial distribution? What is the expiration date for this lot?

If successfully implemented, your responses to Observations 1, 2, 5, 7, and 8 appear to satisfactorily address those observations. You should be prepared to demonstrate the that these corrections have been put into effect during any follow-up inspection.

The violations identified above are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all applicable regulations and provisions of the Act. Federal agencies are advised of the issuance of all Warning Letters about drugs and medical devices, so that they may take this information into account when considering the award of contracts. Additionally, pending export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your response should be sent to Mark Lookabaugh, Compliance Officer, U.S. Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, MA 02180. If you have any questions concerning this matter, please contact Mr. Lookabaugh at **781.596.7751**.

Sincerely,

Gail Costello
Director
New England District